M & G PRODUCTS CO., LTD.

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:

M & G Products Co., Ltd.

No. 55 South Gangdong Road, Yangzhong, Jiangsu, China

We declare under our sole responsibility that

the medical device:

Sterilization reel and pouch

model:

KMNHR-050200 50mm*200m; KMNHR-075200 75mm*200m; KMNHR-100200 100mm*200m; KMNHR-150200 150mm*200m; KMNHR-200200 200mm*200m; KMNHR-250200 250mm*250m; KMNHR-300200 300mm*200m; KMNHR-350200 350mm*200m; KMNHR-400200 400mm*200m; KMNHR-450200 450mm*200m; KMNHR-500200 500mm*200m; KMNHR-550200 550mm*200m;

KMNHR-600200 600mm*200m;

of class:

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according to annex IX of directive 93/42/EEC European Directive (and further modifications and integrations-ref.: 2007/47/CE European directive).

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declarationis valid in connection with the "final inspection report" of the device. /

The device is sold in non-sterile packaging

Conformity assessment procedure: /

Directive 93/42/EEC Annex VII,

EC-representative name: Caretechion GmbH

EC-representative address: Niederrheinstr. 71, 40474 Düsseldorf, Deutschland Germany

Tel:0211 300 366 18 Fax:0211 300 366 19

Notified Body: /

TÜV Rheinland LGA Products GmbH Tillystraße 2

90431 Nürnberg Deutschland

CE 0197

Yangzhong October 26, 2022

Place, date

General Manager

Name and function

